

### **INTERVIEW SUMMARY**

The Examiner is thanked for the courtesies extended during the telephonic interview conducted with the undersigned on October 31, 2006. A proposed amendment to claims 1, 5, and 7 was discussed. At the interview, it was agreed that the amendment to claims 1, 5, and 7 reflected above overcomes the rejection under 35 USC § 112, second paragraph.

### **REMARKS**

The Specification has been amended to specifically refer to the deposit of the strain *Candida kefyr* (*Candida macedoniensis*) IFO 0960 with the National Institute of Technology and Evaluation ("NITE"), Department of Biotechnology, 2-5-8 Kazusakamatari, Kisarazu-shi, Chiba, 292-0818 Japan. This amendment is made merely to update the specification to reflect the transfer of the deposited material from the Institute of Fermentation, Osaka (IFO), 17-85 Juso-homachi 2-chome, Yodogawa-Ku, Osaka 532-8686 Japan to NITE and does not add any new matter. (See Exhibit A.)

Claims 1, 5, and 7 have been amended as set forth above to recite, *inter alia*, "Molecular mass: 61,300  $\pm$  5,000 Da as determined by gel filtration" and "A single subunit having a molecular mass of 45,000  $\pm$  5,000 Da as determined by SDS-polyacrylamide gel electrophoresis." Support for these amendments is found in the specification at, for example, page 1, lines 17 - 24 and page 5, line 18 - page 8, line 5 and in original claims 1, 5, and 7, respectively. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (I) (8<sup>th</sup> ed. Rev. 5, August 2006, pp. 600-84 and 600-92).

Claims 2-4 have been amended to recite "The enone reductase according to claim ..." These amendments are made only for the purpose of clarity and do not change the scope of the claims in any way.

Claims 15-19 have been added. Support for these claims is found in the specification at, for example, page 1, lines 17 - 24 and page 2, line 12 - page 3, line 25 and in original claims 1 and 7. *See id.*

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

### **Objection**

Claims 1, 5, and 7 were objected to for "using parenthesis." (Paper No. 07212006 at 2.) Claims 1, 5, and 7 have been amended to remove parenthesis. Accordingly, the objection has been rendered moot and should be withdrawn.

Claims 2-4 were objected to for "being of improper independent form." (*Id.*) As suggested by the Examiner, claims 2-4 have been amended to recite "The enone reductase according to claim ...." Accordingly, the objection has been rendered moot and should be withdrawn.

### **Indefiniteness Rejection**

Claims 1, 5, and 7 were rejected under 35 USC § 112, second paragraph. (Paper No. 07212006 at 4.) In making the rejection, the Examiner asserted that the claims "recite the limitation of 'an enone reductase having the following physico-chemical properties: a) molecular mass: 61,300  $\pm$  5,000 Da (**consisting of one**

**subunit** having a molecular mass of  $45,000 \pm 5,000$  Da)', which is confusing." (*Id.*) (Emphasis original.) The Examiner further asserted that "the same polypeptide/subunit has two different molecular weights under two very different biochemical conditions...." (*Id.* at 5.) Claims 2-4, 6, and 8-14 were also rejected because they "depend (directly or indirectly) from the broader claims 1, 5, and 7." (*Id.*)

Claims 1, 5, and 7 have been amended to recite, *inter alia*, "Molecular mass:  $61,300 \pm 5,000$  Da as determined by gel filtration" and "A single subunit having a molecular mass of  $45,000 \pm 5,000$  Da as determined by SDS-polyacrylamide gel electrophoresis." As the Examiner agreed during the interview, these amendments remove any asserted "confusion" in the claims. Accordingly, the rejection of claims 1-14<sup>1</sup> has been rendered moot and should be withdrawn.

### **Enablement Rejection**

Claim 4 was rejected under 35 USC § 112, first paragraph, on the asserted grounds that the specification is not enabling with regard to evidence of the deposit of *Candida kefyr* (*Candida macedoniensis*) IFO 0960. (Paper No. 07212006 at 3.) In response, the following statement is provided upon information and belief:

The *Candida kefyr* (*Candida macedoniensis*) IFO 0960 strain was deposited under the terms of the Budapest Treaty at the National Institute of Technology and Evaluation ("NITE"), Department of Biotechnology, 2-5-8

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<sup>1</sup> A "claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." 35 USC § 112, paragraph 4. Accordingly, the amendment of independent claim 1, 5, or 7 can be imputed to the rejected dependent claims that depend therefrom.

Kazusakamatari, Kisarazu-shi, Chiba, 292-0818 Japan<sup>2</sup> under Deposit No.: NBRC 0960 on April 24, 2002. Confirmation of this deposit is attached. (Exhibit A.)

This deposit was made without any restrictions on public availability.

All restrictions imposed by the depositor on the availability to the public of the deposited material mentioned will be irrevocably removed upon the granting of a patent.

As noted above, the Specification has been amended to specifically refer to the deposited material.

It is respectfully submitted that, the confirmation of the deposit and the statements set forth above overcome this rejection. See 37 CFR §§ 1.803(a)(1) and 1.809 and MPEP §§ 2404.03, 2405, 2406, 2406.01, 2410 - 2410.02, 2411, 2411.02, and 2411.05 (8<sup>th</sup> ed. Rev. 5, August 2006, pp. 2400-6 to 2400-19). Accordingly, the rejection has been rendered moot and should be withdrawn.

### **Provisional Obvious-Type Double Patenting Rejections**

Claims 1-4 and 7-14 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 07212006 at 6.) The Examiner alleges that claims 1-4 and 7-14 of the instant application "are unpatentable over claims 6-8 of copending Application No. 10/528,960." (*Id.*) The Examiner stated that the rejection is "provisional ... because the conflicting claims have not in fact been patented." (*Id.*)

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<sup>2</sup> MPEP § 2405 lists the International Depository Authorities (IDA) as of July 2001. Subsequent to that date, NITE was recognized by WIPO as an IDA. See WIPO, Budapest Notification No. 215 dated April 1, 2004 (recognizing NITE as an IDA). (Exhibit B.)

The present application has a filing date (February 14, 2003), earlier than that of U.S. Application No. 10/528,960 (September 19, 2003). No terminal disclaimer is or will be required in the present application.

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, ***the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.***

\* \* \*

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, ***the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer.***

Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based upon the other two, it is not sufficient to file a terminal disclaimer in only one of the applications addressing the other two applications. Rather, ***an appropriate terminal disclaimer must be filed in at least two of the applications*** to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other. MPEP §§ 804(I)(B)(1) (8<sup>th</sup> ed. Rev. 5, August 2006, pp. 800-17 to 800-18). (Emphasis added.)

As the earliest of the three applications that the Examiner asserts have conflicting claims (see below), the present application does not require a terminal disclaimer. If this rejection and/or the following rejection are the only remaining rejections in the present application, they must be withdrawn

Accordingly, if this rejection and/or the following rejection are the only remaining rejections, it is respectfully requested that they be withdrawn.

Claims 7-14 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 07212006 at 6.) The Examiner alleges that claims 7-14 of the instant application "are unpatentable over claims 1-21 of copending Application No. 10/505,314." (*Id.*) The Examiner stated that the rejection is "provisional ... because the conflicting claims have not in fact been patented." (*Id.* at 7.)

The present application has a filing date (February 14, 2003) earlier than that of U.S. Application No. 10/505,314 (February 15, 2003). No terminal disclaimer is or will be required in the present application. As the earliest of the three applications that the Examiner asserts have conflicting claims (*see above*), the present application does not require a terminal disclaimer. If this rejection and/or the previous rejection are the only remaining rejections in the present application, they must be withdrawn.

Accordingly, if this rejection and/or the previous rejection are the only remaining rejections, it is respectfully requested that they be withdrawn.

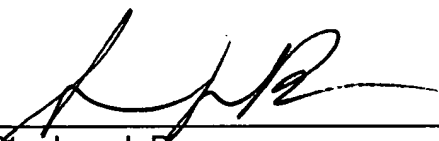
Application No.: 10/505,396  
Amendment Dated: November 20, 2006  
Reply to Office Action Dated: July 26, 2006

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the objections and rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 20, 2006.

  
Stephen J. Brown, Reg. No. 43,519

Respectfully submitted,

By:   
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独立行政法人  
製品評価技術基盤機構  
National Institute of Technology and Evaluation

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## CERTIFICATE

Department of Biotechnology (DOB) of the National Institute of Technology and Evaluation,  
hereby certify that:

1. *Candida kefyr*, NBRC 0960 was received by the Institute for Fermentation, Osaka (IFO), the rights to which were transferred to DOB by IFO on April 24, 2002. Since that date, this microorganism has been maintained and is available in the public culture collection at DOB.  
The strain deposited as NBRC 0960 is identical to that deposited as IFO 0960.
2. A viable sample of the microorganism described in clause 1 above is provided to any person who has residence in Japan, outside Japan, or other regions in accordance with the procedures designated by DOB, except where such provision is restricted under Japanese law.

Date: August 19, 2004

Certificate No.: 2004-MC011

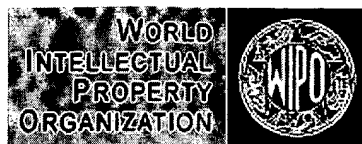
Signed by

Masahiro Miyazaki, Director-General

National Institute of Technology and Evaluation  
Department of Biotechnology  
2-5-8 Kazusakamatari, Kisarazu-shi  
Chiba, 292-0818 Japan







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## **Budapest Notification No. 215**

### **Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure**

#### **Communication by the Government of Japan Relating to the Acquisition of the Status of International Depositary Authority by the National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD)**

The Director General of the World Intellectual Property Organization (WIPO) presents his compliments to the Minister for Foreign Affairs and has the honor to notify him of the receipt from the Government of Japan, on March 10, 2004, of a written communication dated March 8, 2004 (ref. ST/WP/92), relating to the acquisition of the status of International Depositary Authority by the National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD), which states that this Depositary Institution is located on the territory of Japan and includes a Declaration of Assurances to the effect that the Institution complies and will continue to comply with the requirements concerning the acquisition of the status of International Depositary Authority specified in Article 6(2) of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, done at Budapest on April 28, 1977, and amended on September 26, 1980.

Pursuant to Article 7(1)(b), the National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD) shall acquire the status of International Depositary Authority under the Budapest Treaty on April 1, 2004, that is, on the day indicated in the communication.

April 1, 2004

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Communication from the Government of Japan Relating to the Appointment of the National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD) as an International Depositary Authority

[Original: English]

#### **COMMUNICATION**

The Permanent Mission of Japan to the international organizations in Geneva presents its compliments to the World Intellectual Property Organization (WIPO) and has the honor to transmit herewith, in relation to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the communication from its home Government regarding the acquisition of the status of International Depositary Authority by the National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD).

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#### **ANNEX**

##### *Declaration of Assurances*

The Government of Japan guarantees that the National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD) complies and will continue to comply with the requirements specified in Article 6(2) of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The Government of Japan understands that this communication shall be disclosed to all the Contracting States and Intergovernmental Industrial Property Offices.

##### *Information on the Depositary Authority*

## 1. Name and address:

National Institute of Technology and Evaluation,  
 Patent Microorganisms Depositary (NPMD)  
 2-5-8 Kazusakamatari  
 Kisarazu-city  
 Chiba 292-0818  
 Japan  
 Telephone: (81) 438 20 55 80  
 Facsimile: (81) 438 20 55 81  
 E-mail: npmd@nite.go.jp

## 2. Detailed information as to the capacity of NPMD to comply with the requirements in Article 6(2):

NPMD is a part of the Department of Biotechnology (DOB) in the National Institute of Technology and Evaluation (NITE) founded in 2001. DOB also consists of three organs, that is, Biological Resource Center, Biotechnology Development Center and Genome Analysis Center. Twenty-four thousand microorganisms and 15,000 DNA clones have been deposited with it and 11,000 cultures have been released.

DOB has been performing its duties as one of the biological resource centers under the Organisation for Economic Co-operation and Development (OECD).

Among its 160 staff members, 11 are to be engaged in the depositary occupation. Since all staff members are government officials, it is assured to comply with the duty of secrecy, being impartial and objective. NPMD has a fire-and-quake-proof building for depositary operations and backup generation systems for emergency purposes.

## 3. Kinds of microorganisms accepted as patent deposits:

NPMD is to accept bacteria, actinomycetes, yeasts and fungi, which belong to biosafety levels 1 and 2 according to the NITE classification, and archaea, bacteriophages and plasmids (DNA clones).

For deposits of recombinant DNA molecules, the highest acceptable physical containment level is P2 as described in the Ministerial Ordinance stipulating Containment Measures to be Taken in Type 2 Use of Living Modified Organisms for Research and Development (2004), which is based on the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (2003).

## 4. Schedule of fees:

	JPY
Original deposit (storage for 30 years)	139,000
New deposit	19,000
Communication under Rule 7.6	2,000
Issuance of a viability statement where a viability test is requested	34,000
Issuance of a viability statement on the basis of the last viability test	2,000
Furnishing of a sample	6,000
Attestation under Rule 8.2	2,000
Issuance of some kinds of certification	2,000

## 5. Official language: Japanese

## 6. The date referred to in Article 7(1)(b) is April 1, 2004